K071271

OCT 23 2007

510(k) Summary

Preparation Date: October 17, 2007

Applicant/Sponsor: Biomet Spine (aka EBI, names may be used interchangeably)
100 Interpace Parkway
Parsippany, NJ 07054

Contact Person: Becky Earl/Debra L. Bing

Proprietary Name: Biomet® Cable System

Common Name: Cable System

Classification Name: Cerclage, Bone Fixation (CFR 888.3010)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Medtronic/Sofamor Danek Atlas™ Cable System, K920201, K925812, K030816; Songer Spinal Cable System, K922952.

Device Description: The Biomet® Cable System is available in either titanium or stainless steel, consisting of a flexible, multi-strand, medical grade titanium alloy (Ti-6Al-4V, ASTM F-136) or a medical grade stainless steel (316LVM, ASTM F-138) cable. The systems are available in both single and double styles. The cable is locked into place via a pre-loaded crimp. Instruments for the Biomet® Cable System include a Cable Tensioner, a Cable Crimper, and a Cable Cutter. The titanium system is compatible with other medical grade implants made of titanium and the stainless steel system is compatible with other stainless steel implants, whenever "wiring" may help secure the attachment of other implants.

Indications for Use: The Biomet® Cable System is indicated for use whenever a conservative or non-implant surgery is deemed insufficient to improve the medical condition of the patient. The System can be utilized anywhere monofilament wire has been previously indicated.

1. Spinal applications include spinal degenerative surgery, as an adjunct to spinal fusions and sublaminar and intraspinous process wiring for trauma applications. The Biomet® Cable System may also be used with instrumentation involving the correction of scoliotic, kyphotic, and lordotic deformities. The titanium system is compatible with other titanium implants and the stainless steel system with stainless steel implants, wherever "wiring" may help secure the attachment of other implants.
2. Trochanteric reattachment after trochanteric osteotomy, following total hip arthroplasty.
3. Sternotomy indications include the "re-wiring" of sternums following osteotomy.
4. Trauma surgery indications include olecranon, ankle, patella, and some shoulder fracture rewiring.

Summary of Technologies:
The technological characteristics (materials, design, sizing, indications) of the Biomet® Cable System are similar or identical to the predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Manufacturing Corp
% Ms. Becky Earl
Regulatory Specialist
P. O. Box 587
Warsaw, IN 46581

OCT 23 2007

Re: K071271
Trade/Device Name: Biomet® Cable Ssystem
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: October 17, 2007
Received: October 18, 2007

Dear Ms. Earl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

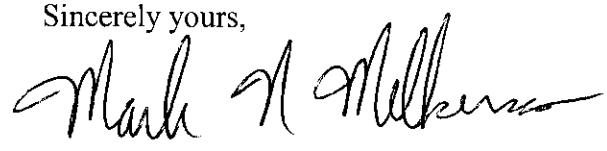
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: Biomet® Cable System

Indications for Use: The Biomet® Cable System is indicated for use whenever a conservative or non-implant surgery is deemed insufficient to improve the medical condition of the patient. The System can be utilized anywhere monofilament wire has been previously indicated.

1. Spinal applications include spinal degenerative surgery, as an adjunct to spinal fusions and sublaminar and intraspinous process wiring for trauma applications. The Biomet® Cable System may also be used with instrumentation involving the correction of scoliotic, kyphotic, and lordotic deformities. The titanium system is compatible with other titanium implants and the stainless steel system with stainless steel implants, wherever "wiring" may help secure the attachment of other implants.
2. Trochanteric reattachment after trochanteric osteotomy, following total hip arthroplasty.
3. Sternotomy indications include the "re-wiring" of sternums following osteotomy.
4. Trauma surgery indications include olecranon, ankle, patella, and some shoulder fracture rewiring.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __NO___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071271